

Guidelines for Categorizing Significant Deficiencies and OLAW Reporting

Investigators using animals for research should be aware that serious deficiencies in their compliance with regulations pertaining to the health and welfare of the animals may require the ACUC to report those deficiencies to the NIH Office of Laboratory Animal Welfare. The following guidelines have been established to assist ACUC members in the designation of deficiencies. However, the ACUC has broad discretion in applying this standard. Deficiencies are discussed at regularly convened ACUC meetings. At that time, a final determination as to the nature of the deficiency is made. Formal minority opinions will be attached to the final semiannual facility inspection/program report if desired by the dissenting member.¹

MINOR DEFICIENCY

Minor deficiencies in animal facilities include infrequent findings of peeling or chipped paint, burnt-out light bulbs, missing floor drain covers, and similar problems for which immediate solutions generally are not necessary to protect life or prevent distress. Repeated detection of minor, area-specific problems, however, should suggest to management that there are substantial program deficiencies resulting in a failure to develop effective policies or plans or to take corrective actions to prevent recurrences.

Examples of minor deficiencies related to animal care and well-being may include (but are not limited to):

- Minor proposal deviation;
- Cage cards not containing the required information;
- Dates not properly labeled on feed containers.

SIGNIFICANT DEFICIENCY

The term "significant deficiency," used in the PHS Policy and the USDA Animal Welfare Regulations, refers to any facility or program deficiency that is or may be a threat to the health or safety of animals. Program or facility deficiencies, including accidents and natural disasters, which cause injury, death, or severe distress to animals are by definition "significant." Although it is not possible to provide an exhaustive listing of examples, some illustrations of significant deficiencies may include (but are not limited to):

- Failures in heating, ventilating, and air conditioning systems and their associated electrical systems;
- Inoperative watering systems;
- General power failures of sufficient duration to affect critical areas such as isolators, barriers, surgical suites, and intensive care units.

Examples of significant deficiencies related to animal care and well-being may include (but are not limited to):

- Use of animals without ACUC approval;
- Conducting animal-related activities without appropriate ACUC review and approval;
- Failure of personnel to adhere to ACUC reviewed and approved institutional policies and procedures.

OLAW REPORTING

The PHS Policy identifies three areas that require prompt reporting to OLAW: (a) any serious or continuing noncompliance with the PHS Policy; (b) any serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals*; and (c) any suspension of an activity by the ACUC. **Determination that a problem falls within the meaning [letter or spirit] of either (a) or (b) requires a degree of judgment by the ACUC.** The language used in the Policy was chosen purposely to permit the judicious application of professional judgment by the ACUC in determining what incidents should be reported to OLAW. Based on these criteria, the ACUC has developed the following examples of occurrences that may [at the ACUCs discretion] meet these reporting criteria:

(a) Serious or continuing noncompliance with the PHS Policy

- Failure to correct situations identified in previous semiannual evaluations as significant deficiencies;
- Conducting animal-related activities without appropriate ACUC review and approval;
- Failure of personnel to adhere to ACUC reviewed and approved institutional policies and procedures.

(b) Serious deviation from the provisions of the *Guide*

- Conditions that jeopardize the health or well-being of animals, including accidents, natural disasters and mechanical failures resulting in actual harm or death to animals;
- Shortcomings in programs of veterinary care, occupational health or training, identified during semiannual program review and not corrected within the institutionally determined time frame.

(c) Suspension of an activity by the ACUC

- An ACUC intervention that results in the temporary or permanent interruption of an activity involving animals [not related to lapses in the ACUC review and approval of renewals resulting in animals being transferred to an animal holding proposal until an investigator's study is reviewed and approved by the ACUC]

Attached is the **Guidance for Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals** for additional guidance.

Adapted from *Frequently Asked Questions About PHS Policy. Contemporary Topics. 1997; 36(2): 47.*

¹ *The IACUC Handbook. Eds. Sliverman, Suckow, Murthy. CRC Press, 2000.*

Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals

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This Notice provides guidance to Public Health Service (PHS) awardee institutions and Institutional Animal Care and Use Committees (IACUCs) on the prompt reporting requirements of the PHS Policy on Humane Care and Use of Laboratory Animals (Policy) (<http://grants.nih.gov/grants/olaw/references/phspol.htm>). This guidance is intended to assist IACUCs and Institutional Officials in determining what, when, and how situations should be reported under IV.F.3 of the Policy, and to promote greater uniformity in reporting. This Notice supersedes the January 12, 1994 Dear Colleague letter from the former Division of Animal Welfare, Office for Protection from Research Risks (now the Office of Laboratory Animal Welfare, or OLAW).

Background

PHS Policy, IV.F.3, requires that:

"The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- a) any serious or continuing noncompliance with this Policy;
- b) any serious deviation from the provisions of the *Guide [for the Care and Use of Laboratory Animals]* ; or
- c) any suspension of an activity by the IACUC."

IACUC suspensions of activities are cited at IV.C.6 and 7 of the Policy, and require a convened meeting of a quorum of the IACUC and the vote of a majority of the quorum present. The Institutional Official must review the reasons for suspension in consultation with the IACUC, take appropriate corrective action and report that action with full explanation to OLAW.

All institutions with Animal Welfare Assurances are required to comply with the provisions of IV.F.3. The Institutional Official signing the Assurance, in concert with the IACUC, is responsible for this reporting.

Reporting promptly to OLAW under IV.F.3 serves dual purposes. Foremost, it ensures that institutions deliberately address and correct situations that affect animal welfare, PHS-supported research, and compliance with the Policy. In addition, it enables OLAW to monitor the institution's animal care and use program oversight under the Policy, evaluate allegations of noncompliance, and assess the effectiveness of PHS policies and procedures.

The underlying foundation of the PHS Policy is one of institutional self-evaluation, self-monitoring and self-reporting. Public Law 99-158 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>) requires that institutions be provided a reasonable opportunity to take corrective action before a grant or contract is suspended or terminated, and it is OLAW's role to assess whether the corrective actions reported by institutions under IV.F.3 are adequate. OLAW will assist the reporting institution in developing definitive corrective plans and schedules if necessary. Compliance actions affecting an award are rare because

institutions are usually able to address incidents successfully and take appropriate actions to prevent recurrence.

Guidance on Prompt Reporting

A comprehensive list of definitive examples of reportable situations is impractical. Therefore, the examples below do not cover all instances but demonstrate the threshold at which OLAW expects to receive a report. Institutions should use rational judgment in determining what situations meet the provisions of IV.F.3 and fall within the scope of the examples below, and consult with OLAW if in doubt. OLAW welcomes inquiries and discussion and will provide guidance with regard to specific situations. Situations that meet the provisions of IV.F.3 and are identified by external entities such as the United States Department of Agriculture or the Association for Assessment and Accreditation of Laboratory Animal Care International, or by individuals outside the IACUC or outside the institution, are not exempt from reporting under IV.F.3.

Examples of reportable situations:

- conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;
- conduct of animal-related activities without appropriate IACUC review and approval;
- failure to adhere to IACUC -approved protocols;
- implementation of any significant change to IACUC -approved protocols without prior IACUC approval as required by IV.B.7.;
- conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);
- conduct of official IACUC business requiring a quorum (full Committee review of an activity in accord with IV.C.2 or suspension in accord with IV.C.6) in the absence of a quorum;
- conduct of official IACUC business during a period of time that the Committee is improperly constituted;
- failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
- chronic failure to provide space for animals in accordance with recommendations of the *Guide* unless the IACUC has approved a protocol-specific deviation from the *Guide* based on written scientific justification;
- participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f;
- failure to monitor animals post -procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);
- failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);
- failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO 2);
- failure of animal care and use personnel to carry out veterinary orders (e.g., treatments); or
- IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide* , or the institution's Animal Welfare Assurance.

OLAW recognizes that there may be levels of morbidity and mortality in virtually any animal-related activity, including those associated with the care and use of animals in research, testing, and teaching that are not the result of violations of either the Policy or the *Guide* . OLAW offers the following examples of situations which may *not* meet the threshold for reporting, based on consideration of the circumstances by the IACUC.

Examples of situations *not* normally required to be reported:

- death of animals that have reached the end of their natural life spans;
- death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate;
- animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed;
- animal death or injuries related to manipulations that fall within parameters described in the IACUC -approved protocol; or

- infrequent incidents of drowning or near-drowning of rodents in cages when it is determined that the cause was water valves jammed with bedding (frequent problems of this nature, however, *must* be reported promptly along with corrective plans and schedules).

Time Frame for Reporting

Institutions should notify OLAW of matters falling under IV.F.3 promptly, i.e., without delay. Since IV.F.3 requires a full explanation of circumstances and actions taken and the time required to fully investigate and devise corrective actions may be lengthy, OLAW recommends that an authorized institutional representative provide a preliminary report to OLAW as soon as possible and follow-up with a thorough report once action has been taken. Preliminary reports may be in the form of a fax, email, or phone call. Reports should be submitted as situations occur, and not collected and submitted in groups or with the annual report to OLAW.

Information to Be Reported

Include as many of the following items of information as possible in the initial contact with OLAW. A follow-up report may address anything not known at the time of the initial report and should summarize the institution's corrective action. If a long term plan is necessary, describe the plan and include a reasonable schedule. This information will allow OLAW to assess the circumstances and actions taken to correct and prevent recurrence of the situation.

Information to be included:

- Animal Welfare Assurance number (<http://grants.nih.gov/grants/olaw/assurance/300index.htm>);
- relevant grant or contract number(s) if the situation is related to an activity directly supported by PHS;
- a full description of any potential or actual affect on PHS-supported activities if the situation is not directly supported by the PHS but is in a functional, programmatic, or physical area that could affect PHS-supported activities (e.g., inadequate program of veterinary care, training of technical/husbandry staff, or occupational health; inadequate sanitation due to malfunctioning cage washer; room temperature extremes due to HVAC failures);
- full explanation of the situation, including what happened, when and where, the species of animal(s) involved, and the category of individuals involved (e.g., principal or co-principal investigator, technician, animal caretaker, student, veterinarian, et c.);
- description of actions taken by the institution to address the situation; and
- description of short - or long-term corrective plans and implementation schedule(s).

Preliminary and final reports should be made to:

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